Instructions for Use

CIM® Octa Swiper 0.05 mL Monolithic Column (2 µm channels)

CIM Convective Interaction Media®
BIA-128.5122-2

SARTORIUS

Contents

1. About These Instructions for Use

These instructions are part of the device. They apply to the device product number indicated on the cover page.

2. Safety

⚠WARNING
Denotes a hazard that may result in death or severe injury if it is not avoided.

⚠CAUTION
Denotes a hazard that may result in moderate or minor injury if it is not avoided.

NOTICE
Denotes a hazard that may result in property damage if it is not avoided.

2.1. Intended Use

CIM® Octa Monoliths are miniaturized eight-in-line columns, designed for automatic and parallel chromatographic screening of process development parameters. The columns are used with a robotic liquid handling workstation with a needle. Inside CIM® Octa columns are CIM® monoliths with homogeneous channel size and surface chemistry. The properties of the stationary phase are directly comparable to CIM® preparative chromatographic columns, making CIM® Octa a robust tool in early process development stages.

The CIM® Swiper is an advanced chromatography product designed for efficient nucleic acid purification within an acidic to neutral pH range. Utilizing multimodal weak anion exchanging properties, it offers exceptional selectivity between RNA, DNA, and proteins, making it ideal for complex samples. This product efficiently purifies single-stranded RNA of various sizes and modalities at neutral pH and ambient temperature, delivering optimal results without the need for extreme conditions.

2.2. Safety Note

Follow the guidelines in this Instructions for Use. Improper use may result in malfunction, personal injury, or damage of the product or material. Follow safety instructions, wear gloves, safety glasses, and a lab coat during operation.

3. Technical Data

Column chemistry	Multimodal (anion exchange-hydrogen bonding)
Channel radius	1050 nm (950 nm – 1150 nm)
Support matrix	Poly(glycidyl methacrylate -co- ethylene dimethacrylate)
Monolith dimensions	Diameter: 5 mm; length: 2.5 mm; bed volume (CV): 0.05 mL
Column format	Row of eight-in-line columns, material: polypropylene (PP) and polyethylene (HDPE)
Operating parameters	Flow rate between 30-270 cm/h | 2 - 18 CV/min | 100 - 900 µl/min
Maximum pressure	0.8 MPa, 8.0 bar, 116 psi
Operating temperature	4 °C (39 °F) to 40 °C (104 °F)
Chemical stability	All commonly used aqueous buffers, 1 M NaOH, 0.1 M HCl, 8 M urea, 6 M guanidine hydrochloride and 20% ethanol solution. Avoid oxidizing agents. Avoid prolonged use of concentrated acids (more than 0.1 M) like hydrochloric, sulphuric or acetic acid.
Recommended pH	Working range 2–11, cleaning in place 1–13.7
Storage conditions	2 °C (36 °F) to 25 °C (77 °F); 20% ethanol in 20 mM sodium phosphate at pH 2.5.
Shelf life	N.D.

4. Installation

Remove the product from its shipping box or crate and place on a flat surface. Carefully inspect the product for any damage that may have occurred during shipping. Immediately report any such damage to your vendor and the courier. The product is shipped in the designated storage solution at ambient temperature and should be stored upon receiving as stated under Technical Data.

NOTICE
Do not store the product below 0 °C (32 °F).

5. Getting Started

The CIM Octa columns require a fully automated robotic system and are operated with a needle. CIM Octa columns are supplied as a row of eight-in-line columns. Each row of columns comes with a holder for easier handling. Each individual column is removable from the holder. Operating parameters can be found under Technical Data. Before use, remove the top and bottom cover seals. Place the columns in the array plate to a tight fit and start the process by removing storage solution.

5.1. General Recommendations

The following are general guidelines to consider when working with chromatography. The guidelines may not apply to specific column chemistry or sample properties.

- Treat loading material appropriately (e.g. pre-treat, filter, concentrate / dilute, etc.). For more details, please refer to the Guideline 'Pre-treatment of complex biological samples before column purification and regeneration procedures for columns with increased back pressure' (biaseparations.com/en/library/guidelines).
- Always use freshly prepared mobile phases, filtered through 0.2 µm filter, compatible with mobile phases.
- Air bubbles will not disturb the stationary phase and can be washed out of the column. However, drying the monolith risks damaging the stationary phase.
- Surfactants can improve recoveries in virus purification. Non-ionic surfactants will not interact with ion exchange chromatography media. Non-UV-absorbing (at working wavelengths) surfactants will improve the baseline signal.
- Ensure all components of the system used are compatible with the working solutions (e.g. sodium hydroxide, organic solvents, high salt concentrations, etc).

NOTICE
Always ensure mobile phases are compatible before mixing them or applying consecutively on the column. Examples of in-compatible buffers are: magnesium ion-containing buffers and sodium hydroxide (forms precipitate), acetonitrile and sodium hydroxide (forms ammonia and acetate), ammonium acetate and sodium hydroxide (potential formation of explosive atmosphere). Wash the column with water or another compatible solution when using two incompatible solutions consecutively.

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6. Operating the Column

6.1. Equilibration

The column should be equilibrated with a suitable counter-ion. Binding buffer should have the same or similar composition to the loaded sample. To speed up equilibration, a buffer containing a higher concentration of the appropriate ion may be used (e.g. the elution buffer), as described here.

1. Wash the column with 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of elution mobile phase (which contains elevated salt concentration). For weak ion exchangers, an extended contact time is recommended (by reducing the flow rate to < 0.5 CV/min or a hold step after the flush).
3. Wash the column with at least 10 CV of binding mobile phase. The composition of this mobile phase should be similar to the sample composition.

6.2. Strip | Regeneration

A strip is typically implemented in the purification run to remove tightly-bound sample components. It is common to use the same approach as the elution: elevated salt concentration (e.g. 2 M NaCl), change in pH (low pH or high pH solution), or other.

7. Cleaning | Maintenance

Cleaning and maintenance of the column may improve its lifetime and increase reproducibility. Sample properties should be taken into account for column cleaning.

7.1. Cleaning in Place (CIP)

Column cleaning is recommended between purification runs or cycles. A reduced flow rate is suggested for column cleaning to extend contact time with the cleaning and neutralisation-equilibration solutions (between 0.1 and 0.5 CV/min).

⚠CAUTION
Remain below the maximum pressure specified in Technical Data.

⚠CAUTION
Ensure compatibility between the current column solution and cleaning solutions (see examples in General Recommendations).

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1. If needed wash the column with 10 CV of water to prevent mixing of incompatible buffers.
2. Wash the column with at least 10 CV of cleaning solution 0.1 M NaOH and 1 M NaCl (combined).
3. Wash the column with 10 CV of water.
4. Wash the column with at least 10 CV of a neutralisation-equilibration solutionor until pH at the column outlet reaches the buffer pH. 0.5 M sodium phosphate buffer pH 6.5 or 1 M sodium acetate pH 5.5 are recommended to efficiently displace the counter ion. Other concentrated buffers (e.g. 0.1–0.5 M buffer, pH 5–6) can be used but their use needs to be validated. To perform another purification run, proceed with column equilibration, otherwise proceed to Storage Procedure.

Note: NaOH forms a precipitate with bivalent metal cations (e.g. Mg2+, Ca2+). Precipitation causes a gradual pressure increase over consecutive runs until complete column blockage. The precipitate can be dissolved with a 0.1 M HCl wash. Consecutive washes with acid will have negative impact on column lifetime. To prevent precipitation, wash the column with at least 5 CV of water or a compatible buffer before and after NaOH.

8. Storage

The column can be stored in working buffers overnight. Before storage, follow instructions in Cleaning in Place section that will guide you through cleaning and neutralisation protocol.

1. If needed wash the column with at least 5 CV of deionized water.
2. Wash the column with at least 10 CV of 25 mM Na-phosphate, pH 2.5 or until pH and conductivity are stable.
3. Wash the column with at least 5 CV of storage solution containing 20 % ethanol in 20 mM Na-phosphate, pH 2.5 or until pH and conductivity are stable. Note: Reduce the flow rate when using viscous solvents (such as ethanol) to avoid a pressure increase. Note: Any deviation from the recommended storage solution (i.e. 20 % ethanol in 20 mM

Na-phosphate, pH 2.5) or storage protocol could affect column performance.
4. Seal the column with blind fittings and store at the temperature specified in Technical Data. If there is a possibility of biological contamination from the sample it is recommended to store the column between 2 °C (36 °F) and 8 °C (46 °F).

Note: Consider compatibility between sample and mobile phases to avoid precipitation inside the column (e.g. alkaline solutions, such as NaOH).

9. Troubleshooting

Problems arising during the analysis are usually related to the device, sample, mobile phase, or the instrumentation. It is advisable to use an elimination approach to exclude possible causes. Please refer to our troubleshooting guide (biaseparations.com/en/library/guidelines).

10. Decommissioning | Transportation

If there is reason to return the product, complete a Return Form (biaseparations.com/en/terms-conditions) and contact help.bia@sartorius.com.

Contaminated samples used during the process that could cause biological or chemical hazards are potentially hazardous substances. If the product has come into contact with hazardous substances, steps must be taken to ensure proper decontamination and declaration.

Procedure
Decontaminate the product. The operator of the product is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

11. Ordering Information

Transferring the workflow to a different scale or format (analytical, screening) is simple with CIM®. Contact your local support to find the appropriate products.

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The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

Last updated

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